



## **Hepatitis in Kentucky: Updates on Epidemiology, Testing, and Treatment**

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On behalf of the KY Viral Hepatitis Prevention Programs, see our February 2016 edition of the KY Hepatitis Connections. Inside this edition, you will find recently released hepatitis news and articles on various topics concerning hepatitis screening, testing, latest treatments, and opportunities for viral hepatitis continuing professional education.

As always, feel free to forward, copy and/or distribute this newsletter to other professionals in your network.

Your knowledge and input are greatly valued, as we are committed to keeping you up to date on shared progress in the medical community on viral hepatitis and its impact on families throughout the Commonwealth.

Kathy J. Sanders, RN MSN

# SAVE THE DATE!

## July 26, 2016

### Kentucky 3<sup>rd</sup> Annual Viral Hepatitis Conference

Kentucky Rural Health Association,  
in partnership with Kentucky Department for Public  
Health's Adult Viral Hepatitis Prevention Program  
and the Kentucky Immunization  
Program is proud to present

## Hepatitis: Breaking the Silence

Embassy Suites in Lexington, Kentucky

This conference aims to educate attendees on prevention, diagnosis  
and treatment of those affected by hepatitis B and hepatitis C.

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Additional conference registration information will soon follow



# **HCV: CDC Health Advisory**

## **CDC Urging Dialysis Providers and Facilities to Assess and Improve Infection Control Practices to Stop Hepatitis C Virus Transmission in Patients Undergoing Hemodialysis**

The Centers for Disease Control and Prevention (CDC) has received an increased number of reports of newly acquired hepatitis C virus (HCV) infection among patients undergoing hemodialysis. Infection control lapses in dialysis care could expose patients to HCV. Any case of new HCV infection in a patient undergoing hemodialysis should prompt immediate action. CDC is urging dialysis providers and facilities to:

- 1) Assess current infection control practices and environmental cleaning and disinfection practices within the facility to ensure adherence to infection control standards;
- 2) Address any gaps identified by the assessments;
- 3) Screen patients for HCV, following CDC guidelines, to detect infections, determine treatment potential, and halt secondary transmission; and
- 4) Promptly report all acute HCV infections to the state or local health department.

### **Background**

CDC has received an increased number of reports of acute HCV infection among patients undergoing hemodialysis. Between 2014 and 2015, CDC has been contacted about 36 cases of acute HCV infection in 19 different hemodialysis clinics in eight states. While investigations are ongoing, so far, HCV transmission between patients has been demonstrated at nine of those clinics, based on epidemiologic and viral sequencing evidence. Lapses in infection control (e.g., injection safety, environmental disinfection, and hand hygiene) were commonly identified at these facilities. Although the exact means of transmission could not be discerned, these lapses all could potentially contribute to HCV transmission. The increase in acute HCV infections might be due, in part, to improved screening and awareness of the potential for HCV infection in the hemodialysis setting. Regardless, this increase underscores the widespread potential for patients to acquire serious infections during dialysis care. Dialysis facilities should actively assess and continuously improve their infection control, environmental cleaning and disinfection, and HCV screening practices, whether or not they are aware of infections in their clinic. Any case of new HCV infection in a patient undergoing hemodialysis is likely to be a healthcare-associated infection and should be reported to public health authorities in a timely manner. A recent publication describes a dialysis facility where an outbreak of HCV continued for five years before being detected, highlighting the importance of HCV screening to identify these infections early and prevent further transmission. HCV transmission can be prevented when proper infection prevention and environmental disinfection practices are consistently followed.

### **Recommendations**

In response to the increased identification of HCV transmission in dialysis clinics, CDC recommends the following actions be followed:

- Evaluate infection control practices in each facility and ensure adherence to infection control standards.
  - CDC has checklists and audit tools (<http://www.cdc.gov/dialysis/prevention-tools/index.html>) that providers can use to assess their practices, identify gaps, and improve infection control practices to protect patients.

For the full Report, go to: <http://emergency.cdc.gov/han/han00386.asp>

# HCV: IN THE NEWS

## How the Epidemic of Drug Overdose Deaths Ripples Across America

Deaths from drug overdoses have jumped in nearly every county across the United States, driven largely by an explosion in addiction to prescription painkillers and heroin.

Some of the largest concentrations of overdose deaths were in Appalachia and the Southwest, according to new [county-level estimates](#) released by the Centers for Disease Control and Prevention.

The number of these deaths reached a new peak in 2014: 47,055 people or the equivalent of about 125 Americans every day.

### **Deaths from overdoses are reaching levels similar to the HIV epidemic at its peak.**

The death rate from drug overdoses is climbing at a much faster pace than other causes of death, jumping to an average of 15 per 100,000 in 2014 from nine per 100,000 in 2003.

The trend is now similar to that of the human immunodeficiency virus, or HIV, epidemic in the late 1980s and early 1990s, said Robert Anderson, the CDC's chief of mortality statistics. HIV deaths rose in a shorter time frame, but their peak in 1995 is similar to the high point of deaths from drug overdoses reached in 2014, Mr. Anderson said. HIV, however, was mainly an urban problem. Drug overdoses cut across rural-urban boundaries.

### **Workplace injuries may drive rising addiction in Appalachia.**

Appalachia has been stricken with overdose deaths for more than a decade, in many ways because of prescription drug addiction among its workers.

West Virginia and neighboring states have many blue-collar workers, and "in that group, there's just a lot of injuries," said Dr. Carl R. Sullivan III, the director of addiction services at the West Virginia University School of Medicine.

"In the mid-1990s, there was a social movement that said it was unacceptable for patients to have chronic pain, and the pharmaceutical industry pushed the notion that opioids were safe," he said.

A few years ago, as laws were passed to address the misuse of prescription painkillers, addicts began turning to heroin instead, he said. Because of a lack of workers needed to treat addicts, overdose deaths have continued to afflict states like West Virginia, which has the highest overdose death rate in the nation.

"Chances of getting treatment in West Virginia are ridiculously small," Dr. Sullivan said. "We've had this uptick in overdose deaths despite enormous public interest in this whole issue."

Read More: [http://www.nytimes.com/interactive/2016/01/07/us/drug-overdose-deaths-in-the-us.html?\\_r=1](http://www.nytimes.com/interactive/2016/01/07/us/drug-overdose-deaths-in-the-us.html?_r=1)

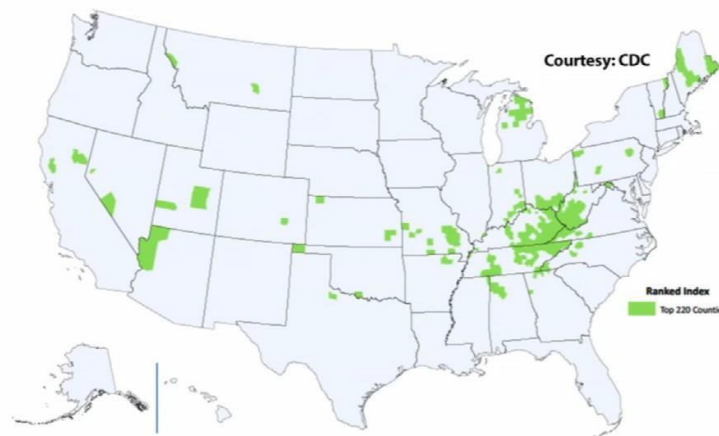
## CDC researchers say much of Kentucky at risk for HIV outbreak

It was March of last year when Indiana's governor declared a public health emergency in Scott County, Indiana.

The number of HIV cases had skyrocketed. The virus largely spread among IV drug users sharing needles. Now, more than 180 people have been affected, many of them also testing positive for Hepatitis C.

"I think it raised awareness all over the nation," said Kentucky Public Health Senior Deputy Commissioner Dr. Kraig Humbaugh.

WDRB News has obtained a map from the CDC that shows other areas that are vulnerable to an outbreak.



The document states, "Through this analysis, CDC sought to identify U.S. counties where persons who inject drugs (PWID) appear especially vulnerable to the rapid spread of HIV or Hepatitis C infection, if introduced into this population."

According to the map, some parts of southern Indiana are at risk, as well as much of the Appalachian region of Kentucky.

Read More: <http://www.wdrb.com/story/30980679/cdc-researchers-say-much-of-kentucky-at-risk-for-hiv-outbreak>

## Jessamine County needle-exchange program gains final approval

Jessamine County will now be home to just the fourth syringe-exchange program in the state, as a result of a vote Tuesday by the fiscal court. The Jessamine County Fiscal Court voted 4-2 at its regular meeting to approve the Jessamine County Health Department's proposal. The fiscal court's approval was the last step needed to make the syringe exchange a reality, after having already received approval from the Jessamine County Board of Health and the Nicholasville City Commission.

Read More: [http://www.centrankynews.com/jessaminejournal/news/local/jessamine-needle-exchange-program-gains-final-approval/article\\_dfbfa9dc-befc-11e5-86a4-5bb637034b0a.html?mode=story](http://www.centrankynews.com/jessaminejournal/news/local/jessamine-needle-exchange-program-gains-final-approval/article_dfbfa9dc-befc-11e5-86a4-5bb637034b0a.html?mode=story)

## Column: Why NKY can't wait for needle exchange

It's been 10 months since Gov. Steve Beshear signed the heroin reform bill, Senate Bill 192, into law. One measure of the law was to allow, for the first time ever in Kentucky, operation of syringe access exchange programs to reduce the threat of infectious diseases spread by intravenous drug use.

In the 10 months since the law was passed, staff at the Northern Kentucky Health Department have brought together partners from the community and resources from across the country to develop a model syringe access exchange program. The proposed program is both efficient and optimizes the public health impact of such services – their ability to connect IV drug users to the health care system and addictions treatment. It would operate with existing staff at the health department's county health centers.

It received unanimous approval from the District Board of Health. The program has funding in place for its first year of operation and staff has received much of the required training. In the 10 months since the law was passed, elected officials in Louisville, Lexington, and Pendleton County have approved such programs in those areas, and public health officials have implemented them. Louisville's program opened in June, Lexington and Pendleton County's began in September.

In the 10 months since the law was passed, Northern Kentucky's IV drug users have continued to share needles. A survey conducted by the health department over the summer found that more than 85 percent of users surveyed share needles at least some of the time. Even more concerning is local IV drug users have indicated that they often share needles until they break or are too dull to use.

Since the law was passed, almost 800 people in Northern Kentucky have been diagnosed with hepatitis C and more than 100 have been diagnosed with hepatitis B. Northern Kentucky was featured in a *New York Times* article in July about its hepatitis C rates, which are the highest in the nation. While a syringe access exchange program won't eliminate these viruses, it can reduce their spread. Read More:

<http://www.cincinnati.com/story/news/local/boone-county/2016/01/24/column-nky-wait-needle-exchange/79275926/>

## People in Northern Kentucky More Likely than Rest of State to Know Heroin User

People in Northern Kentucky are for more likely than those in the rest of the state to know someone who uses heroin. According to information released Tuesday by Interact for Health and the Foundation for a Healthy Kentucky, more than 1 in 10 Kentucky adults (13 percent) know someone with problems as a result of heroin use. This is about the same as in 2014 (11 percent), but it is an increase since 2013, when only 9 percent of adults knew someone who had problems due to heroin use.

In Northern Kentucky, nearly three times as many adults (35 percent) reported that they knew someone who had problems due to heroin use, the highest in the state. The number in Northern Kentucky has risen since 2014, when it was 26 percent.

"These higher numbers may be due in part to heightened awareness in Northern Kentucky, but there is no doubt that heroin use is a crisis in our region," said Lynne Saddler, M.D., M.P.H., District Director of Health for the Northern Kentucky Health Department. Read More:

<http://www.rcnky.com/articles/2016/01/19/people-northern-kentucky-more-likely-rest-state-know-heroin-user>

# Funding ban on needle exchanges effectively lifted

Congress effectively lifted the nation's long-standing ban on federal funding for needle exchange programs, which allow intravenous drug addicts to trade dirty syringes for clean ones in the hope of preventing disease.

The measure was quietly tucked into the omnibus spending package signed by President Obama last month. Though federal funds still can't be used for the syringes themselves, they can go toward the costlier expenses associated with these programs, such as staff, vans, substance use counseling, referral to treatment and outreach in at-risk communities.

"We think this is fantastic news," says Leana Wen, health commissioner in Baltimore, which has distributed more than 8 million clean syringes through a needle exchange operating for two decades. "We know needle exchanges reduce the transmission of disease. Congress has made a critical first step in helping every state implement this evidence-based policy that has proven to save lives."

Opponents have long argued that needle exchanges enable addicts to keep using. Congress first banned the use of federal funds for these programs in 1988, lifted the prohibition in 2009 and reinstated it in 2011. The latest change came at the suggestion of U.S. Rep. Hal Rogers, R-Ky., and Sen. Mitch McConnell, R-Ky., ensured the language remained in the Senate version of the spending bill, their spokespeople say.

"The opioid epidemic is having a devastating effect on communities throughout Kentucky and the nation," McConnell's office said in a statement. "As more people inject drugs like heroin, rates of Hepatitis C and HIV have been on the rise. To help address this issue, Senator McConnell worked with Chairman Rogers to pass legislation to provide flexibility so that certain counties in Kentucky may be able to access federal funds for their treatment and education efforts."

"Congressman Rogers supports efforts in Kentucky and elsewhere to mitigate the spread of devastating diseases, like HIV and (hepatitis) C, and the associated health care costs," says Danielle Smoot, communication director for Rogers. Though he still doesn't want federal money going to the needles themselves, she says, "He believes federal resources can effectively be used for needle exchange programs that focus on education and treatment to help end the cycle of dependency and curb an outbreak of needle-related diseases."

Under the law, she says, the U.S. Centers for Disease Control and Prevention will work to identify at-risk communities where federal funds can be used.

It's likely that parts of Kentucky will be determined to be at risk. The state has been hit hard by prescription drug and heroin abuse and suffers more than 1,000 drug overdose deaths each year. Nearby Indiana experienced its worst-ever HIV outbreak last year — 184 cases in the southeastern region, most linked to addicts shooting up the powerful painkiller Opana. The center of that outbreak was Austin, Ind., which has a population of 4,200 and a higher incidence rate of HIV than any country in sub-Saharan Africa, according to CDC Director Tom Frieden.

A recent Indiana state law allows needle exchanges under certain circumstances when a community, such as Austin, is wracked by an epidemic of HIV or hepatitis C. Indiana officials declined comment on the recent change of the federal funding ban but have said needle exchanges can effectively slow the spread of disease but only as part of a comprehensive strategy against addiction and IV drug abuse.

Read More: <http://www.usatoday.com/story/news/nation/2016/01/07/funding-ban-needle-exchanges-effectively-lifted/78420894/>

## Three more Kentucky counties, two of them rural, recently approved needle exchanges, making six counties with them

The approval of exchanges in Carter and Elliott counties, in northeastern Kentucky, creates a major rural beachhead in a state where officials have said rural officials will be slow to adopt the strategy of preventing HIV, hepatitis and other diseases transmitted by illicit drug users.

The major obstacle is a widespread belief that needle exchanges enable drug users, despite studies that say otherwise. That has created another big hurdle, lack of federal funding. However, Congress removed that obstacle last month at the behest of two Kentuckians: Senate Majority Leader Mitch McConnell and U.S. Rep. Hal Rogers, chair of the House Appropriations Committee.

The two Republicans had opposed federal funding for needle exchanges, but recently led the charge to get Congress to lift a ban that was enacted in 1988, lifted in 2009 and reinstated in 2011. The latest change was included in the omnibus spending package passed in December. The measure still doesn't allow federal funds to be spent on the syringes themselves, but it can be spent on related costs such as staff, transportation, counseling, treatment referral, and outreach.

Not only does the lifting of this ban potentially bring much needed dollars into Kentucky to help pay for the exchanges, but the support of two top Republicans and the federal government could go a long way in convincing local governments to support needle exchanges in the state.

Read More: <http://kyhealthnews.blogspot.com/2016/01/three-more-kentucky-counties-two-of.html>

## The 2016 Hepatitis C Drug Approval Outlook

*Here's what's in store this year for new hepatitis C therapies, as well as approvals for new uses of existing treatments.*

This promises to be another banner year for the expansion of treatment options for people living with hepatitis C virus (HCV). Numerous regimens are either awaiting U.S. Food or Drug Administration (FDA) approval, or in the case of already-approved treatments, for the green light for use by new populations of individuals.

Most imminently, the FDA is expected to issue a decision by January 28 about Merck's application for its once-daily fixed-dose combination tablet of the NS3/4A protease inhibitor grazoprevir and the NS5A replication complex inhibitor elbasvir to treat genotypes 1, 4, and 6 of the virus. The FDA granted breakthrough status to the combo tablet for the treatment of individuals with genotype 1 of the virus who have end-stage kidney disease and are on dialysis, and for those with genotype 4.

The FDA also granted the treatment priority review status. This designation is given to investigational treatments for serious conditions that would offer a significant improvement in safety or effectiveness over other treatments on the market. The status shortens the standard review period from 10 months to six months.

Read More: [http://www.hepmag.com/articles/2016\\_outlook\\_2502\\_28295.shtml](http://www.hepmag.com/articles/2016_outlook_2502_28295.shtml)

# Hep C Drugs in 2016: More Combos and Lower Cost

Hepatitis C treatment has improved dramatically in the past few years. More than ever before, eliminating the Hepatitis C virus from the bloodstream is now accompanied by favorable odds. Efforts to eradicate this virus have been steadily gaining momentum, as the pharmaceutical industry has made Hepatitis C drug development a priority. In 2016, we anticipate this trend will continue. Newer, safer, more effective and more affordable treatments are expected to emerge, besting the progress made in 2015.

## Progress

Hepatitis C drug progress over the past three years is impressive:

- In 2012, the standard of care for Hepatitis C infection was combination treatment with pegylated interferon and ribavirin; a regimen that lasted about six months, was associated with severe side effects and was only about 50 percent effective.
- In 2015, the standard of care was Harvoni (sofosbuvir and ledipasvir), Viekira-Pak and ribavirin, Daklinza and Sovaldi, or Olysio and Sovaldi for three months – and is between 80 and 95 percent effective.

Read More: <http://www.hepatitiscentral.com/news/hep-c-drugs-in-2016-more-combos-and-lower-cost/?eml=hepcen242>

## FDA Grants Priority Review to New Gilead Hep C Combo Tablet

The U.S. Food and Drug Administration (FDA) has granted priority review status to Gilead Sciences' investigational pangenotypic hepatitis C virus (HCV) fixed-dose combination tablet, which includes Sovaldi (sofosbuvir) and velpatasvir. The designation secures a target decision date of June 28, 2016.

Gilead applied for approval of Sovaldi/velpatasvir on October 28, 2015 to treat those with genotypes 1 through 6 of hep C.

The FDA has already given the combination tablet a breakthrough therapy designation, which is given to investigational therapies that may offer major advances over existing treatments.

Sovaldi, which was approved in October 2013, is a nucleotide analog polymerase inhibitor. Velpatasvir is a pan-genotypic NS5A inhibitor.

To read a Gilead press release, see: <http://www.gilead.com/news/press-releases/2016/1/gilead-announces-us-fda-priority-review-designation-for-sofosbuvirvelpatasvir-for-treatment-of-all-genotypes-of-chronic-hepatitis-c-infection>

## AbbVie initiates multiple trials for ABT-493/ABT-530 for HCV

AbbVie announced on January 15, 2016 the initiation of six global phase 3 clinical trials evaluating the safety and efficacy of its ribavirin-free regimen, ABT-493 and ABT-530, for the treatment of hepatitis C virus infection genotypes 1 through 6.

ABT-493, a pan-genotypic NS3/4A protease inhibitor, and ABT-530, a pan-genotypic NS5A inhibitor (AbbVie), will be dosed to approximately 1,600 patients globally enrolled in four ENDURANCE trials and two EXPEDITION studies, according to the release.

The ENDURANCE studies will evaluate the regimen in patients with HCV without cirrhosis for up to 12 weeks. The EXPEDITION studies will evaluate the regimen in difficult-to-treat patient populations with chronic HCV.

“We believe AbbVie's work in hepatitis C has contributed to the transformation of HCV care over the last few years,” Michael Severino, MD, executive vice president of research and development and chief scientific officer at AbbVie, said in the release. “Our journey continues with the initiation of these phase 3 studies, which we hope will help us meet the needs of an even broader range of patients living with hepatitis C.”

Read More: [http://www.healio.com/hepatology/hepatitis-c/news/online/%7Bcfd302bc-e307-4b2b-b818-d78ca8537d7c%7D/abbvie-initiates-multiple-trials-for-abt-493abt-530-for-hcv?utm\\_source=maestro&utm\\_medium=email&utm\\_campaign=hepatology+news](http://www.healio.com/hepatology/hepatitis-c/news/online/%7Bcfd302bc-e307-4b2b-b818-d78ca8537d7c%7D/abbvie-initiates-multiple-trials-for-abt-493abt-530-for-hcv?utm_source=maestro&utm_medium=email&utm_campaign=hepatology+news)

## A promising antiviral inside the Hepatitis C Virus

A study published on January 5<sup>th</sup> in the *Biophysics Journal* reveals that a peptide derived from the Hepatitis C virus (HCV) kills a number of viruses while leaving the hosts cells unharmed by differentiating between the molecular make up of their membrane. The peptide was found to be highly effective against a range of cholesterol-containing viruses including West Nile, dengue, measles, and HIV virus.

It is a known fact that HCV  $\alpha$ -helical (AH) peptide has a broad range of anti-viral properties. This is the property that allows the peptide to hijack the host cell structures for HCV replication and it also produces ruptures in the viral membranes, exposing the viral genome to host enzyme that further destroy the pathogens.

Due to the lack of knowledge on why the AH peptide selectively attacks the viral envelope and leaves the host cell unharmed, there has been a road block in the development of therapies which exploits this property.

Keeping this in mind, senior study author Atul Parikh of the University of California, Davis, and Nanyang Technological University, Singapore says “Although there are many antiviral drugs on the market, a common problem is that the virus learns how to evade them, becoming resistant to the drug treatment. There is a growing recognition that new classes of antiviral drugs that target multiple viruses are needed. Because the HCV-derived peptide appears to meet this need, we reason it targets the Achilles’ heel of viruses—a lipid coating or membrane envelope less likely to become resistant to drugs targeting them”.

Read More: <http://biotechin.asia/2016/01/19/a-promising-antiviral-inside-the-hepatitis-c-virus/>

## Direct-acting antivirals could reduce HCV prevalence by 80%

Novel direct-acting antiviral (DAA) therapies could reduce the prevalence of hepatitis C virus (HCV) by more than 80%, suggesting that HCV infections could be eliminated in the U.S. if enhanced screening and treatment efforts targeted high-risk populations, according to a new study.

Interferon-free DAAs have opened a new frontier in HCV treatment, raising the possibility of not only preventing HCV-associated complications and deaths, but also interrupting transmission among people who inject drugs (PWIDs) and potentially eliminating HCV altogether.

"The key finding is that a four-fold increase to the number of patients treated each year could virtually eliminate HCV from the non-injecting population within a decade," senior author Jeffrey Townsend, associate professor of biostatistics at Yale University in the School of Public Health, told *Medical Economics*. More modest increases in screening and treatment would also markedly reduce new infections and mortality, he said.

Read More: <http://medicaleconomics.modernmedicine.com/medical-economics/news/direct-acting-antivirals-could-reduce-hcv-prevalence-80>

## Drug Overdoses Propel Rise in Mortality Rates of Young Whites

Drug overdoses are driving up the death rate of young white adults in the United States to levels not seen since the end of the AIDS epidemic more than two decades ago — a turn of fortune that stands in sharp contrast to falling death rates for young blacks, a New York Times analysis of death certificates has found.

The rising death rates for those young white adults, ages 25 to 34, make them the first generation since the Vietnam War years of the mid-1960s to experience higher death rates in early adulthood than the generation that preceded it.

The Times analyzed nearly 60 million death certificates collected by the Centers for Disease Control and Prevention from 1990 to 2014. It found death rates for non-Hispanic whites either rising or flattening for all the adult age groups under 65 — a trend that was particularly pronounced in women — even as medical advances sharply reduce deaths from traditional killers like heart disease. Death rates for blacks and most Hispanic groups continued to fall.

Rising rates of overdose deaths and suicide appear to have erased the benefits from advances in medical treatment for most age groups of whites. Death rates for drug overdoses and suicides “are running counter to those of chronic diseases,” like heart disease, said Ian Rockett, an epidemiologist at West Virginia University.

Read More: [http://www.nytimes.com/2016/01/17/science/drug-overdoses-propel-rise-in-mortality-rates-of-young-whites.html?\\_r=3](http://www.nytimes.com/2016/01/17/science/drug-overdoses-propel-rise-in-mortality-rates-of-young-whites.html?_r=3)

## **Grazoprevir Plus Elbasvir in Treatment-Naive and Treatment-Experienced Patients with Hepatitis C Virus Genotype 1 Infection and Stage 4-5 Chronic Kidney Disease (The C-SURFER Study): A Combination Phase 3 Study**

Patients with end-stage renal disease (ESRD) have limited options for concomitant treatment of hepatitis C. Standard therapies, such as interferon, ribavirin, and pegylated interferon, have been successfully used in patients with normal renal function. Patients with ESRD, however, have not benefited from these therapies, primarily because of their toxic effects.

Patients with ESRD and hepatitis C have higher mortality than those without co-occurring infection, and renal transplant recipients have lower graft survival rates in the presence of untreated hepatitis C. These statistics have heightened the urgency of developing novel agents to treat hepatitis C in this selected and highly susceptible population.

The current study (C-SURFER) looked at the safety and efficacy of two novel antiviral agents against hepatitis C: grazoprevir and elbasvir. Both drugs inhibit viral protein activity, and neither drug is excreted through the kidneys. In theory, these medications should have the same therapeutic effectiveness in patients with advanced or end-stage kidney disease as they have been shown to have in patients without renal disease.

Read More: <http://www.medscape.com/viewarticle/857380>

## **Gilead responds to Attorney General Maura Healey's warning to lower Hepatitis C drug price**

Gilead Sciences Inc. has reached out to meet with Massachusetts Attorney General Maura Healey after she called the company out for charging \$1,000 per pill in the U.S. as part of a Hepatitis C drug treatment.

At a Wednesday morning breakfast with biotechnology officials, Healey said that Hepatitis C virus (HCV) rates are rising in Massachusetts as medication like Sovaldi, the drug treatment from Gilead, sits on pharmacy shelves as people can't afford it.

In a letter to the California-based company sent last week, Healey said her office is weighing whether Gilead's pricing may fall under unfair trade practices, a violation of state law.

"Because Gilead's drugs offer a cure for a serious and life-threatening infectious disease, pricing the treatment in a manner that effectively allows [Hepatitis C] to continue spreading through vulnerable populations, as opposed to eradicating the disease altogether, results in massive public harm," she wrote. "My civil enforcement attorneys will continue to examine this potential claim for unfair commercial conduct."

"We agree with the Attorney General about the importance of helping all HCV patients – and that the advent of safe, effective regimens means we can now consider the possibility of eradicating the disease," Amy Flood, Gilead vice president of public affairs said in an email sent to MassLive.com.

Read More: [http://www.masslive.com/news/index.ssf/2016/01/gilead\\_responds\\_to\\_attorney\\_ge.html](http://www.masslive.com/news/index.ssf/2016/01/gilead_responds_to_attorney_ge.html)

## Hep C: Interferon Treatment Triggers Anti-Interferon Antibodies

Patients who have chronic hepatitis C (CHC) who are undergoing antiviral treatments, including those receiving therapies containing pegylated interferon alpha, are likely to develop anti-interferon alpha antibodies (anti-IFN $\alpha$ -AB, Italian researchers found. The study, which was published in the *Journal of Hepatitis Research* in December, 2015, was conducted by Elisabetta Loggi, PhD, of the Department of Medical and Surgical Sciences at the University of Bologna, and colleagues.

The treatment for CHC is steadily improving. The standard of care until quite recently has been based on pegylated interferon alpha (PEG-IFN $\alpha$ ) and ribavirin (RBV). Newer treatments use direct acting antiviral (DAA) agents, but those continue to include PEG-IFN $\alpha$  and RBV.

There are limitations to this therapy, including “suboptimal response rates, severe side effects, and high costs.” And, though the current therapies available are far more effective than those of the past, some cases of CHC cannot be cured. The researchers suggest that “the development of serum anti-IFN $\alpha$ -AB that are able to bind and neutralize the biologic activity of IFN $\alpha$ ” plays a more complex role than currently understood.

The current study is “a retrospective study on stored serum samples from CHC patients.” The researchers state two purposes: “To assess the presence of anti-IFN $\alpha$ -AB during PEG-IFN $\alpha$  plus RBV treatment in CHC” and “To assess the impact of anti-IFN $\alpha$ -Ab on serum levels of IFN $\alpha$  and virological response to treatment.” See more at: <http://www.hcplive.com/medical-news/hepc-interferon-treatment-triggers-anti-interferon-antibodies#sthash.UnoTTETV.dpuf>

## HBV: IN THE NEWS

### Tenofovir Prevents HBV Transmission in Pregnancy

Giving tenofovir to pregnant women with high levels of hepatitis B virus can reduce transmission to children, researchers reported here. In a randomized controlled trial in China, mothers with viral loads above 200,000 IU/mL given tenofovir starting at weeks 30 to 32 of gestation had less viral transmission to their babies, according to Calvin Pan, MD, of NYU Langone Medical Center.

Pan presented the findings at the American Association for the Study of Liver Diseases meeting. Preventing mother-to-child transmission could help reduce global burden of hepatitis B infection and liver cancer, Pan explained. Despite getting appropriate immunoprophylaxis, about 10% to 30% of infants born to highly viremic mothers still become infected with HBV.

More evidence is starting to suggest that antiviral therapy during pregnancy may reduce transmission in highly viremic mothers, but there have not been any large well-designed studies yet, Pan said. And there are certainly few data on using tenofovir to prevent mother-to-child transmission, he added.

World Health Organization guidelines don't currently recommend using antiviral therapy during pregnancy to prevent transmission. To assess whether tenofovir could prevent transmission, Pan and colleagues enrolled 200 women who had HBV DNA levels above 200,000 IU/mL and who were positive for Hepatitis B e antigen (HBeAg).

Read More:

[http://www.medpagetoday.com/MeetingCoverage/AASLD/54806?xid=nl\\_mpt\\_IDSA\\_confreport\\_2015-11-20&eun=g5517831d30r](http://www.medpagetoday.com/MeetingCoverage/AASLD/54806?xid=nl_mpt_IDSA_confreport_2015-11-20&eun=g5517831d30r)

# Increases in Acute Hepatitis B Virus Infections — Kentucky, Tennessee, and West Virginia, 2006–2013

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As many as 2.2 million persons in the United States are chronically infected with hepatitis B virus (HBV) (1), and approximately 15%–25% of persons with chronic HBV infection will die prematurely from cirrhosis or liver cancer (2). Since 2006, the overall U.S. incidence of acute HBV infection has remained stable; the rate in 2013 was 1.0 case per 100,000 persons (3). Hepatitis B vaccination is highly effective in preventing HBV infection and is recommended for all infants (beginning at birth), all adolescents, and adults at risk for HBV infection (e.g., persons who inject drugs, men who have sexual contact with men, persons infected with human immunodeficiency virus [HIV], and others). Hepatitis B vaccination coverage is low among adults: 2013 National Health Interview Survey data indicated that coverage with  $\geq 3$  doses of hepatitis B vaccine was 32.6% for adults aged 19–49 years (4). Injection drug use is a risk factor for both hepatitis C virus (HCV) and HBV. Among young adults in some rural U.S. communities, an increased incidence of HCV infection has been associated with a concurrent increase of injection drug use (5); and recent data indicate an increase of acute HCV infection in the Appalachian region associated with injection drug use (6). Using data from the National Notifiable Diseases Surveillance System (NNDSS) during 2006–2013, CDC assessed the incidence of acute HBV infection in three of the four Appalachian states (Kentucky, Tennessee, and West Virginia) included in the HCV infection study (6). Similar to the increase of HCV infections recently reported, an increase in incident cases of acute HBV infection in these three states has occurred among non-Hispanic whites (whites) aged 30–39 years who reported injection drug use as a common risk factor. Since 2009, cases of acute HBV infection have been reported from more non-urban than urban regions. Evidence-based services to prevent HBV infection are needed.

Data from confirmed cases of acute HBV infection reported to CDC from Kentucky, Tennessee, and West Virginia during 2006–2013, including demographic and risk characteristics were obtained from NNDSS. These states used the CDC/Council of State and Territorial Epidemiologists case definition to identify cases of acute HBV infection.<sup>†</sup> Cases of acute HBV infection were categorized as “urban” if the infected person lived in a metropolitan county with a population  $\geq 50,000$  and as “non-urban” if the infected person lived in a nonmetropolitan county with a population  $< 50,000$ .<sup>§</sup> Data were analyzed by year of report and urban/non-urban county resident status to assess annual incidence (per 100,000 persons), demographic characteristics, and injection drug use in persons with reported acute HBV infections during 2006–2013. To calculate annual incidence, the number of cases reported through NNDSS was used as the numerator and midyear (July) population estimates from the U.S. Census Bureau were used as the denominator. Statistical significance of a monotonic trend in annual incidence of acute HBV infection by urban/non-urban status was tested with the Spearman rank correlation test. A 20% increase in incident HBV infections was observed from 2009 to 2010; therefore, the data are presented for two reporting time periods: 2006–2009 and 2010–2013. Chi-square tests were used to determine whether cases reported during the two time periods differed significantly by demographic characteristics and reported injection drug use. Statistical significance was defined as  $p < 0.05$ .

During 2006–2013, a total of 3,305 cases of acute HBV infection were reported to CDC from Kentucky, Tennessee, and West Virginia. During 2009–2013, incidence of acute HBV infection increased 114% in these three states, but remained stable in the United States overall. Comparing the number of cases of acute HBV infection reported during 2006–2009 and 2010–2013, the proportion of cases among whites and persons aged 30–39 years increased during 2010–2013.

Read More: <http://www.cdc.gov/mmwr/volumes/65/wr/mm6503a2.htm>

## **MMWR – Update: Shortened Interval for Postvaccination Serologic Testing of Infants Born to Hepatitis B-Infected Mothers**

Infants born to hepatitis B-infected mothers receive post-exposure prophylaxis to reduce their risk for perinatal hepatitis B virus (HBV) infection. Post-exposure prophylaxis consists of hepatitis B (HepB) vaccine and hepatitis B immune globulin administered within 12 hours of birth, followed by completion of the 3-dose or 4-dose HepB vaccine series. Post-vaccination serologic testing (PVST) assesses an infant's response to HepB vaccination and has typically occurred at age 9–18 months. This report provides a CDC update recommending shortening the interval for PVST from age 9–18 months to age 9–12 months.

Providers should order PVST (consisting of hepatitis B surface antigen [HBsAg] and antibody to HBsAg [anti-HBs]) for infants born to HBsAg-positive mothers at age 9–12 months (or 1–2 months after the final dose of the vaccine series, if the series is delayed). This recommendation was prompted by the discontinuation of production of Hib/HepB vaccine (Comvax) and new data from the Enhanced Perinatal Hepatitis B Prevention Program supporting PVST 1–2 months after receipt of the last HepB vaccine dose, and at age  $\geq 9$  months.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm>

## **Laboratory Reporting of Pregnancy Status for Hepatitis B-positive Women**

Although some screening studies have estimated that about 95% of pregnant women receive prenatal HBsAg testing, fewer than half of the expected births to HBsAg-positive women are identified. Laboratory reports are only required to have gender and age/date of birth, so pregnancy status is not typically reported to health departments. To help improve identification of HBsAg-positive pregnant women, CDC and partners have worked together to include pregnancy status in laboratory test reports sent to health departments. Four major commercial laboratories are participating in this effort: ARUP Laboratories, LabCorp, Mayo Medical Laboratories, and Quest Diagnostics. An effort is underway to expand this reporting of pregnancy status and engage all laboratories providing HBsAg-testing services.

<http://www.cdc.gov/hepatitis/hbv/pregstatuslabreporting.htm>

## **New Know Hepatitis B Poster – No Warning Signs**

A new resource has been added to the suite of multi-lingual Know More Hepatitis B campaign. This 24x36 poster emphasizes that Hepatitis B often doesn't cause symptoms and encourages Asian Americans to get tested- an early diagnosis are the best way to prevent serious liver problems. This poster is available as a downloadable image in English, Chinese, Vietnamese, and Korean.

<http://www.cdc.gov/knowhepatitisb/materials.htm#posters>

# Reminder:

## Hepatitis C: Perinatal, Newborn infants, and Children Aged Five Years or Less

Health care providers should report:

- All HCV-positive pregnant women;
- All infants born to HCV-positive women;
- All HCV-positive infants and children aged 5 years and younger seen in birthing hospitals, medical practices and clinics

Routine testing for HCV is not recommended for all pregnant women. Pregnant women with a known risk factor for HCV infection should be offered counseling and testing.

Data from the CDC states that approximately 6 out of every 100 infants born to HCV infected women become infected. The risk is greater, 2 to 3 times, if the woman is co-infected with HIV. There is currently no HCV treatment approved for pregnant women.

<http://www.cdc.gov/std/treatment/2010/hepc.htm>

Infants born to HCV-positive mothers should be tested for HCV infection with an HCV RNA test at 2 months of age or older (at a routine well-child visit), or HCV antibody testing can be done at 18 months of age (HCV antibody testing should be delayed until 18 months of age to avoid detecting maternal antibody).

The Kentucky Department for Public Health recommends the use of quantitative HCV RNA tests at 2 months of age or older to assess whether HCV was transmitted to the infant from the HCV-positive mother. <http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm>

Complete and fax the EPID 394 form at  
the end of this newsletter.

Fax forms to 502-696-3803



**HCV  
Reporting**



**Please use the EPID 200 Form for  
reporting acute Hepatitis B and  
Hepatitis C infection.**

**The EPID 394 form is for reporting of perinatal, infants and  
children age five and under with hepatitis B virus infections  
or hepatitis C virus infections.**

**See a copy of the EPID 394 AND the EPID 200  
forms at the end of the newsletter.**



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**Kentucky Public Health**  
Prevent. Promote. Protect.



# Kentucky Reportable Disease Form

Department for Public Health  
Division of Epidemiology and Health Planning  
275 East Main St., Mailstop HS2E-A  
Frankfort, KY 40621-0001

## Hepatitis Infection in Pregnant Women or Child (under the age of five) Fax Form to 502-696-3803

DEMOGRAPHIC DATA						
Patient's Last Name		First	M.I.	Date of Birth	Age	Gender <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Unk
Address		City	State	Zip	County of Residence	
Phone Number	Patient ID Number		Ethnic Origin <input type="checkbox"/> His. <input type="checkbox"/> Non-His.	Race <input type="checkbox"/> W <input type="checkbox"/> B <input type="checkbox"/> A/PI <input type="checkbox"/> Am.Ind. <input type="checkbox"/> Other		
DISEASE INFORMATION						
Describe Clinical Symptoms:			Date of Onset: / /	Jaundice: <input type="checkbox"/> Yes <input type="checkbox"/> No		Date of Diagnosis: / /
Is Patient Pregnant? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, # wks _____			Expected Date of Delivery: / /	Name of Hospital for Delivery:		
Physician Provider Name: Address: Phone:						
LABORATORY INFORMATION						
Hepatitis Markers	Results	Date of test	Viral Load *if applicable	Name of Laboratory		
HBsAg	<input type="checkbox"/> Pos <input type="checkbox"/> Neg	/ /				
IgM anti-HBc	<input type="checkbox"/> Pos <input type="checkbox"/> Neg	/ /				
HBeAg	<input type="checkbox"/> Pos <input type="checkbox"/> Neg	/ /				
IgM anti-HAV	<input type="checkbox"/> Pos <input type="checkbox"/> Neg	/ /				
HCV Antibody	<input type="checkbox"/> Pos <input type="checkbox"/> Neg	/ /				
HCV RNA Confirmation	<input type="checkbox"/> Pos <input type="checkbox"/> Neg	/ /				
SERUM AMINOTRANSFERASE LEVELS						
Patient	Reference	Date of test	Name of Laboratory			
AST (SGOT) U/L	U/L	/ /				
ALT (SGPT) U/L	U/L	/ /				
Mother: Hepatitis Risk Factors <input type="checkbox"/> IDU <input type="checkbox"/> Multiple Sexual Partners <input type="checkbox"/> Tattoos <input type="checkbox"/> STD <input type="checkbox"/> HIV <input type="checkbox"/> Foreign Born/ Country _____ <input type="checkbox"/> Exposure to known HBV/HCV Pos contact			Child: Hepatitis Risk Factors <input type="checkbox"/> Mother HBV Pos <input type="checkbox"/> Household member exposure HBV Pos <input type="checkbox"/> Mother HCV Pos <input type="checkbox"/> Household member exposure HCV Pos <input type="checkbox"/> Foreign Born / Country _____			
Mother: Hepatitis A vaccination history: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused Dates Given: / / Hepatitis B Vaccination history: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused If yes, how many doses <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 Year completed: / / Child: Hepatitis A vaccination history: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused Dates Given: / / Hepatitis B Vaccination history: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused Dates Given: / / Was PEP Infant of Positive HBV mother given at birth? <input type="checkbox"/> Yes <input type="checkbox"/> No						



# Kentucky Reportable Disease Form

Department for Public Health  
Division of Epidemiology and Health Planning  
275 East Main St., Mailstop HS2E-A  
Frankfort, KY 40621-0001

EPID 200 – 9/2014

Disease Name \_\_\_\_\_

## Mail Form to Local Health Department

DEMOGRAPHIC DATA						
Patient's Last Name		First	M.I.	Date of Birth / /	Age	Gender <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Unk
Address		City		State	Zip	County of Residence
Phone Number	Patient ID Number		Ethnic Origin <input type="checkbox"/> His. <input type="checkbox"/> Non-His.	Race <input type="checkbox"/> W <input type="checkbox"/> B <input type="checkbox"/> A/PI <input type="checkbox"/> Am.Ind. <input type="checkbox"/> Other		
DISEASE INFORMATION						
Disease/Organism				Date of Onset / /	Date of Diagnosis / /	
List Symptoms/Comments					Highest Temperature	
					Days of Diarrhea	
Hospitalized? <input type="checkbox"/> Yes <input type="checkbox"/> No		Admission Date / /		Discharge Date / /		Died? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk
Date of Death / /				Hospital Name:		
Is Patient Pregnant? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, # wks _____				School/Daycare Associated? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Name of School/Daycare:				Outbreak Associated? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Food Handler? <input type="checkbox"/> Yes <input type="checkbox"/> No				Person or Agency Completing form:		
Name:				Agency:		
Address:				Attending Physician:		
Address:				Name:		
Phone:				Date of Report: / /		
Phone:				Address:		
LABORATORY INFORMATION						
Date	Name or Type of Test	Name of Laboratory	Specimen Source	Results		
ADDITIONAL INFORMATION FOR SEXUALLY TRANSMITTED DISEASES ONLY						
Method of case detection: <input type="checkbox"/> Prenatal <input type="checkbox"/> Community & Screening <input type="checkbox"/> Delivery <input type="checkbox"/> Instit. Screening <input type="checkbox"/> Reactor <input type="checkbox"/> Provider Report <input type="checkbox"/> Volunteer						
Disease:		Stage		Disease:		Site: (Check all that apply)
<input type="checkbox"/> Syphilis		<input type="checkbox"/> Primary (lesion) <input type="checkbox"/> Secondary (symptoms) <input type="checkbox"/> Early Latent <input type="checkbox"/> Late Latent <input type="checkbox"/> Congenital <input type="checkbox"/> Other		<input type="checkbox"/> Gonorrhea <input type="checkbox"/> Chlamydia <input type="checkbox"/> Chancroid		<input type="checkbox"/> Genital, uncomplicated <input type="checkbox"/> Pharyngeal <input type="checkbox"/> Anorectal <input type="checkbox"/> Other _____
Resistance:						
<input type="checkbox"/> Penicillin <input type="checkbox"/> Tetracycline <input type="checkbox"/> Other _____						
Date of spec. Collection	Laboratory Name	Type of Test	Results	Treatment Date	Medication	Dose